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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,697	10/05/2006	Jurgen Wagner	33714-US-PCT	2925

1095 7590 07/21/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

WEBB, WALTER E

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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07/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,697	Applicant(s) WAGNER ET AL.	
	Examiner WALTER E. WEBB	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 4/7/2008, have been fully considered

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

Claims 1, 3-8 and 13 were rejected under 35 USC 102(b) as being anticipated by Heath et al. This rejection is maintained.

Applicant has amending claims 1 and 6 to recite the phrase "an autoimmune disease other than diabetes mellitus."

However, Heath et al. also teach treating an autoimmune disease other than diabetes mellitus e.g. psoriasis¹. (See col. 13, lines 1-5.) The amended claims remain anticipated by Heath et al.

Claim Rejections - 35 USC § 103

Claims 1-10 and 12-14 remain rejected under 35 USC 103(a) as being unpatentable over Heath et al. as applied to claims 1, 3-8 and 13, and in further view of Albert et al.

¹ Kirby et al., "Novel immune-based therapies for psoriasis." British Journal of Dermatology 2002:146(4);546-551. See abstract.

Applicants submit that the PKC inhibitors of Heath are distinct from the PKC inhibitors of Albert. The Examiner acknowledges the differences between the compounds of Albert and Heath. However, these compounds are alike insofar as they are both PKC inhibitors and they are useful in treating the same diseases such as psoriasis and Alzheimer's.

Applicant argues that one of ordinary skill in the art would not be motivated to use the compound the Heath et al. to treat rheumatoid arthritis, since Heath et al. does not describe rheumatoid arthritis as being an inflammatory disease. Nevertheless, a prior art genus of many species suggests every species falling within that genus. The Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742. Therefore, the artisan would reasonably infer that the compounds of Heath were useful in treating rheumatoid arthritis, since it is an inflammatory disease. The Albert et al. reference offers further support for the treatment of rheumatoid arthritis by PKC inhibitors. Given that the compounds of Albert and Heath are of the same genre and are useful in treating the same diseases, the artisan would reasonably expect the compounds of Heath to also treat rheumatoid arthritis.

Applicant argues that Albert does not teach treatment of rheumatoid arthritis. They argue that Albert instead teaches "that their compounds of formula I can treat T-

cell mediated acute or chronic inflammation such as rheumatoid arthritis.” (See page 10 of Remarks/Arguments.) This argument is contradictory and deemed unpersuasive. Rheumatoid arthritis is clearly listed as an inflammatory disease treatable by the compounds of Albert.

Applicant argues that the artisan would not use the compounds of Heath alone or in combination with another drug to treat rheumatoid arthritis, since there is no indication that the compounds of Heath are equivalents for treating rheumatoid arthritis. However, the compounds of Heath and Albert are equivalent insofar as they are both PKC inhibitors and known to be useful for the same purpose. There is no reliance on Applicant's disclosure for this equivalency. Albert is deemed to be a proper reference for these purposes. Accordingly, the rejection of claims 1-10 and 12-14 as being unpatentable over Heath in view of Albert is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612

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